

Respirator Certification and Post Certification Activities



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PPT Stakeholder Meeting

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Respiratory Protection Regulations

- **OSHA Respiratory Protection Standard (29 CFR 1919.134) requires use of NIOSH approved respirators**
- **NIOSH authority to approve respirators found in 42 CFR 84**

Respirator Certification of Systems

- NIOSH approves *'individual, completely assembled respirators'*
 - 42 CFR 84.30(a)
- NIOSH will not issue approval of *'any respirator component or for any respirator subassembly'*
 - 42 CFR 84.30(b)
- Concept makes it easy to track actual configurations and identify critical performance characteristics

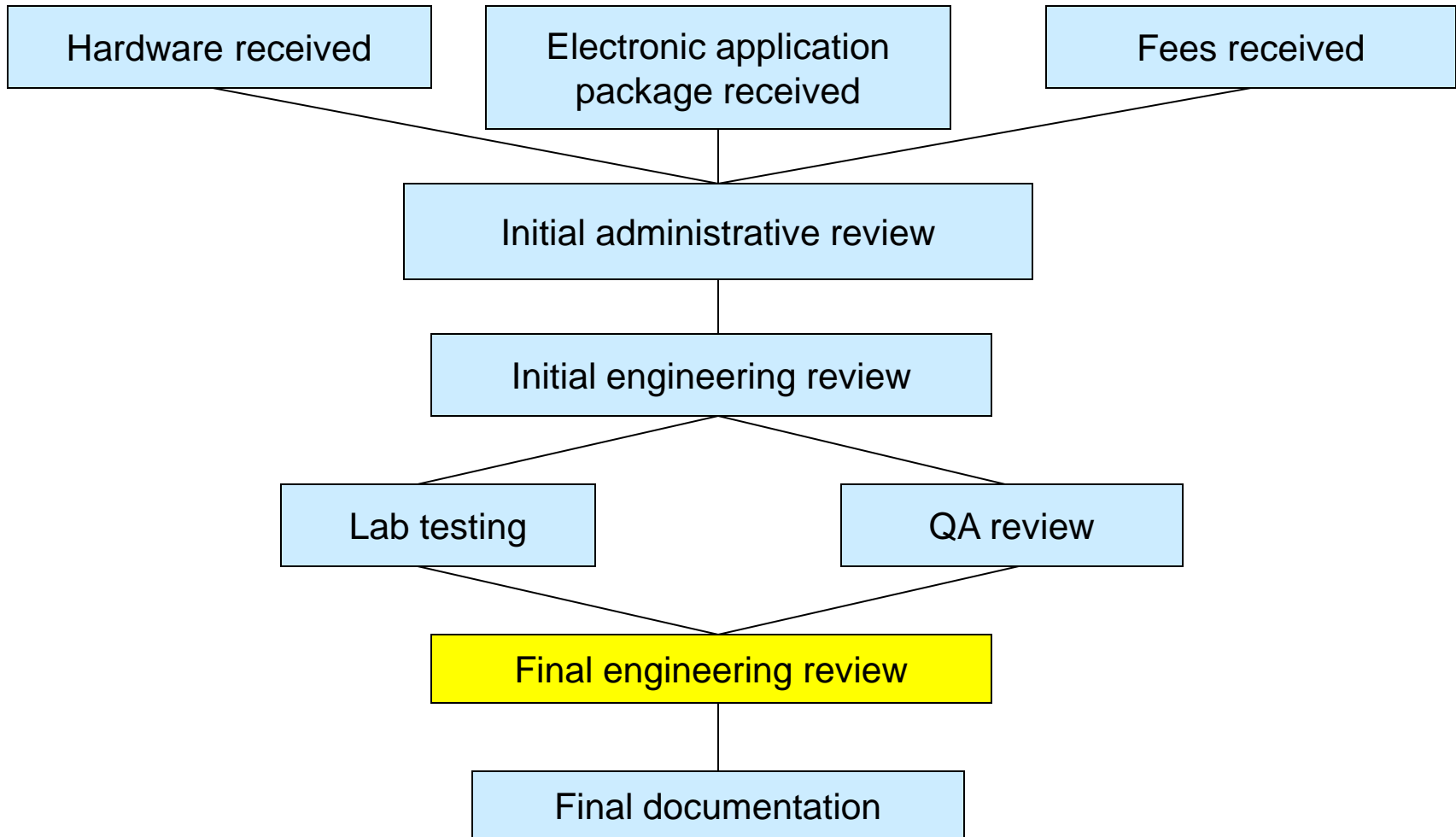


Respirator Certification Program Elements

- **Certification Activities**
- **Technical assistance**
- **Post Certification Activities**
 - Certified Product Investigations
 - Firefighter Investigations
 - Product Audits
 - Manufacturing Site Audits
 - Long Term Field Evaluation



Respirator Certification Process



Final Engineering Review

Final Review

- **Final review of all documentation supporting approval request**
- **Review of NIOSH approval test data**
- **Finalize approval labels**
- **Recommendation made for approval /denial and documentation generated**
- **Update NIOSH internal databases (DEIMS)**
- **Insures that Certified Equipment List (CEL) is updated**

These approval activities confirm certification.

Post Certification Activities

- **Manufacturing Site Audits**

- Two year schedule
- Evaluating approval holder against approved QA plan submitted

- **Product Audits**

- 40-50 per year
- Equipment bought from open market

Post Certification Activities

- **Certified Product Investigations**
 - Initiated by users/approval holder/NIOSH
 - Can result in Stop Sale request/recall/retrofit or some other corrective action
- **Fire Fighter Fatality and Injury Prevention Program**
 - Collaboration with NIOSH DSR
 - Reported by Fire Department or State Agency
 - Evaluation as to whether unit is in an approved condition

Current NIOSH post certification activities focused on filtering facepiece respirators

- **42 Code of Federal Regulations Part 84, Section 84.34 (c) Revocation of certificates of approval**
- **Typical Factors contributing to revocation**
 - Performance Failures
 - Failure to Maintain a Quality System
 - Misleading Advertising
 - Misuse of approval labels

Surgical mask being sold through WalMart Stores in Canada as N95 mask – NIOSH notified Feb 2010

Jiangsu Teyin Nonwoven Fabrics Co., Ltd (JTN)



Misleading Information

Misleading Representation: DuraMax Pro EN149 FFP1 Dust Mask advertised as NIOSH approved N95 – May 5, 2009



Mainstays mask previously sold at Walmart

- Packaging claimed NIOSH N95
- No certified products available by “Mainstays”
- NIOSH investigators searched through photos of numerous failed applications
- It appeared that JTN sold products that had not passed NIOSH testing and tried to sell them under a different name



Recent NIOSH Revocations

Jiangsu Teyin Nonwoven Fabrics Co., Ltd (JTN)

June 22, 2009

- 14 approvals revoked for failure to maintain an acceptable quality control plan
- Can no longer be listed as NIOSH approved
- Can no longer be manufactured, assembled, sold or distributed



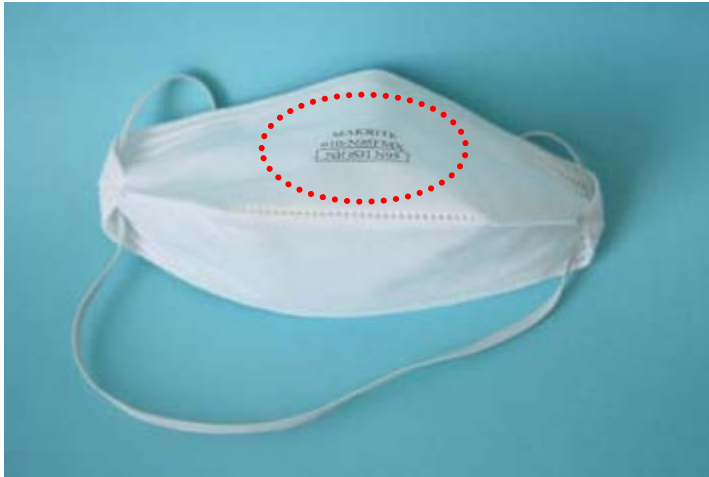
Recent NIOSH Revocations

BeiBei Safety Company, Ltd. (BBE) – July 1, 2009

- **7 approvals revoked for failure to maintain an acceptable quality control plan**
- **Can no longer be listed as NIOSH approved**
- **Can no longer be manufactured, assembled, sold or distributed**



NIOSH Approved Respirators altered to create non-approved Aloha Masks



Disclaimer added to web site: "Our colored masks are made from white stock masks that are N95 certified from the manufacturer in unaltered form. We then apply the decorations in Hawaii and the masks are not resubmitted to NIOSH or the manufacturer for recertification."

Technical Assistance

- **Many calls, letters, emails, faxes**
- **Variety of issues: selection, training, enforcement, verify approval, APF, interchanging parts, etc.**
- **Inquiries from organizations, labor, other government, contractors, general public**

Information Dissemination

- **Letters to All Manufacturers**
 - Policy Changes
 - Clarifications
- **User Notices developed by NIOSH**
 - Inform users of product failures or recalls
- **User Notices developed by Approval Holders**
 - Inform users of product failures or recalls
- **Letters to all Interested Parties**
 - Inform all customers of new initiatives at NIOSH
- **Certified Equipment List and Trusted Source Page**
 - Record of approved products